K022246

X. 510 (k) Summary

AUG 0 2 2002

SUBMITTER:	DePuy AcroMed, Inc. 325 Paramount Drive Raynham, MA 02767
CONTACT PERSON:	Karen F. Jurczak
DATE PREPARED:	July 11, 2002
CLASSIFICATION NAME:	Piston Syringe
PROPRIETARY NAME:	Symphony Graft Delivery System (GDS)
PREDICATE DEVICES:	Symphony Graft Delivery System (K003286, K010320)
INTENDED USE:	The Symphony Graft Delivery System is indicated for the delivery of allograft, autograft, or synthetic bone graft materials to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with I.V. fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements.
MATERIALS:	Acetal Copolymer, 17-4 Stainless Steel, Polycarbonate
PERFORMANCE DATA:	All medical grade materials have undergone biocompatibility testing in accordance with US Pharmacopoeia XXII Class VI guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2002

DePuy AcroMed
Karen F. Jurczak
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K022246
Trade Name: Modification to Symphony Graft Delivery System
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 11, 2002
Received: July 12, 2002

Dear Ms. Jurczak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use

510(k) Number (if known): K022246

Device Name: Symphony Graft Delivery System

Indications For Use:

The Symphony Graft Delivery System is indicated for the delivery of allograft, autograft, or synthetic bone graft materials to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with I.V. fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use:
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022246